K003104

OCT 2 0 2000

510(k) Premarket Notification
Organon Teknika Corporation
BacT/ALERT CSR

510(k) Summary

(a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

Submitter's Name: Organon Teknika Corporation

Submitter's Address: 100 Akzo Avenue
Durham, North Carolina 27712
Submitter's Telephone: (919) 620-2288

Submitter's Contact: Rebecca A. Rivas

Date 510(k) Summary Prepared: August 29, 2000

(a)(2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

Trade or Proprietary Name: BacT/ALERT CSR Reagent

Common or Usual Name: BacT/ALERT CSR Reagent

Classification Name: Microbial Growth Monitor Accessory

(a)(3) **An identification of the legally marketed device to which the submitter claims substantial equivalence;**

Device Equivalent to: Untreated sample from BacT/ALERT FA, FN or PF Culture Bottle.

(a)(4) **A description of the device.**

Device Description: BacT/ALERT CSR is a sedimentation reagent that interacts with the charcoal present in the FAN medium causing agglutination and sedimentation of the majority of the charcoal particles. The charcoal-depleted supernatant may then be sampled for other laboratory procedures such as Gram Stain. The BacT/ALERT CSR has been found to enhance the sedimentation of the charcoal in a sample removed from a BacT/ALERT FAN Bottle for the purposes of a Gram stain.

(a)(5) **A statement of the intended use of the device.**

Device Intended Use: The BacT/ALERT CSR Reagent is used to enhance the settling of the charcoal present in BacT/ALERT FAN Culture Bottles and provide the user with a charcoal-depleted microbial suspension.

(a)(6) A summary of the technological characteristics of the new device in comparison to those of the predicate device.

FEATURES	Specimen treated with BacT/ALERT CSR	Specimen untreated
Recovery of microorganisms	Yes, Equivalent to untreated specimen	Yes
Bottles Used	BacT/ALERT FA,FN or PF	BacT/ALERT FA, FN or PF
Sample Source	Blood, Body Fluids	Blood, Body Fluids

(b)1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.

Testing was performed to establish the recovery of organisms in specimen samples treated with BacT/ALERT CSR as compared to specimen samples untreated with CSR.
Seeded studies were performed using 5 organisms specific for each bottle type.
Testing was also performed to establish potential bioburden levels introduced into specimen sample from BacT/ALERT CSR. The levels were found at such low levels as to be insignificant.

(b)3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).

1. Specimen samples treated with the BacT/ALERT CSR recovered substantially equivalent levels of organisms as compared to untreated specimen samples.

2. Testing showed no significant increase in microbial bioburden levels in the specimen treated with BacT/ALERT CSR.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 0 2000

Ms. Rebecca A. Rivas
Regulatory Affairs Administrator
Organon Teknika Corporation
100 Akzo Avenue
Durham, North Carolina 27712

Re: K003104
Trade Name: BacT/ALERT CSR
Regulatory Class: I
Product Code: LJF
Dated: July 24, 2000
Received: July 26, 2000

Dear Ms. Rivas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

10(k) Number (If known):_____

Device Name: BacT/ALERT CSR

Indications For Use:

BacT/ALERT CSR is used to enhance the settling of the charcoal present in BacT/ALERT FAN Culture Bottles and provide the user with a charoal-depleted microbial suspension.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003104

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)